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The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/534,399
Filing Date: May 10, 2005
Appellant(s): MIYAZAWA ET AL.

Donald E. Townsend and
Donald E. Townsend, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/14/08 appealing from the Office action mailed 1/2/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The Examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment was filed after the final rejection, and no Advisory Action was prepared after the final rejection.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

Statement I of the Appellant's statement of the grounds of rejection to be reviewed on appeal is correct. However, statement II of the Appellant's statement of the grounds of rejection is *incorrect*. Specifically, the final rejection of 1/2/08 has one ground of rejection which is the written description requirement of 35 U.S.C. 112, first paragraph. There are no grounds of rejection which pertain to appellant's statement II.

(7) Claims Appendix

The copy of the appealed claims contained in Appendix I to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the Examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground of rejection is applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, Appellant's have not defined terms a, b, and c in either the specification or the claims. In the absence of a working definition for these terms, Appellant's appear to only have support for the working examples of the specification (Examples 1-3). However, these working examples fail to provide any conclusive data as to the numerical values of a, b, and c; determination of these values require that the commercially available starting materials KF-86, X-22-3939A, and KF-393 are defined in terms of the numerical values of a, b, and/or c. This information is required for Appellant's to have full support of the working examples.

(10) Response to Argument

Applicant's present five issues (pages 13 and 14 of Brief) which are responded to by the Examiner as follows:

Point 1: Whether the specification and/or claims define the terms a, b, and c.

Regarding the claims, there is no implicit or explicit definition of variables a, b, and c. Regarding the specification, paragraphs 0015-0018 of the instant specification describes three polysiloxane structures having repeating units represented by formulae (5), (6) and (7), which are obtained by introducing the phosphorylcholine group of formula (1) to some or all of the amino groups of the polysiloxanes of formulae (2), (3) and (4). Paragraph 0017 goes on to further define the structures according to the R groups and variables n, m, and p. However, variables a, b, and c are not further limited by a numerical range.

Paragraph 0039 of the instant specification teaches that "a, b, and c denote constituent units of the polysiloxane, that is, the polymer has a units, b units, and c units." Paragraph 0040 goes on to teach that "when a, b, and c, are represented by numbers, they denote molar ratios". However, neither of these teachings clearly defines variables a, b, and c. The teaching that a, b, and c are represented by numbers does not satisfy the written description requirement. As stated in the previous Office action, -7 is a number, as is 0. Such numbers clearly satisfy the "definition" provided by the Appellants. Therefore, such phosphorylcholine-containing groups do not even need to be present in order to satisfy the teaching that a, b, and c are represented by numbers.

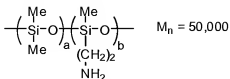
The teachings presented in paragraphs 0015-0018 and 0039 are argued by Appellants as providing adequate written description; however, for reasons provide supra, this is not believed to be persuasive.

Point 2: Whether the working examples provide conclusive data as to the numerical values of a, b, and c.

Appellants argue that the working examples would lead one of ordinary skill in the art to arrive at a numerical value of a, b, and c. Appellants argue that examples 1 and 3 of the instant specification provide support for the values of a, b, and c. Since the polysiloxane starting materials of the examples 1 and 3 are taught to have a molecular weight of 50,000 and 3,000 respectively, and since a ratio of a:b is taught in examples 1 and 3, and since proton NMR spectra are given for examples 1 and 3, a person having ordinary skill in the art would readily be able to determine the actual values for a and b. This argument is not found to be persuasive. Examples 1 and 3 (and example 2) only teach commercial trade names for the polysiloxane starting materials. No information is given regarding the structure of these starting materials other than the average molecular weight. Specifically, a person having ordinary skill in the art does not know the molecular weight of the monomer subunits, the nature of the end-groups, or if any other monomer repeat units are additionally present. Any of these three factors would preclude a person having ordinary skill in the art from arriving at a tangible and accurate value for subunits a, b and c.

Since variable n is not clearly defined in Example 1 one could have many possible structures. As but one example, shown below, shows a situation when n is equal to 2 and when n is equal to 22. Both scenarios are possible given the indefinite structural information provided by Appellants in the working examples. The final values for a and b will be different depending on whether n is equal to 2 or 22 as shown below. Further, the calculations shown below do not take into account the nature of the end groups of the polymer or if other monomer subunits are additionally present.

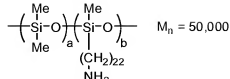
If n is equal to 2



$(\text{Me})_2\text{SiO}$ repeat unit = 74
 $\text{MeSiO}(\text{CH}_2)_2\text{NH}_2$ repeat unit = 104
 ratio of a:b 50:1 by ^1H NMR
 $b = 0.02a$
 $74 \cdot a + (104)(0.02a) = 50,000$
 $74 \cdot a + 2.08a = 50,000$
 $76.08 \cdot a = 50,000$
 $a = 657$

Therefore 657 a units and 13 b units

If n is equal to 22



$(\text{Me})_2\text{SiO}$ repeat unit = 74
 $\text{MeSiO}(\text{CH}_2)_{22}\text{NH}_2$ repeat unit = 384
 ratio of a:b 50:1 by ^1H NMR
 $b = 0.02a$
 $74*a + (384)*(0.02a) = 50,000$
 $74*a + 7.68a = 50,000$
 $81.68*a = 50,000$
 $a = 612$

Therefore 612 a units and 12 b units

As can be shown above, the Examples fail to provide an explicit definition for the values of a and b since the commercially available polymers do not clearly provide an exact structure to a person having ordinary skill in the art, therefore, the values for a and b remain indefinite. Further, while the Appellants argue that arrival at numerical values of a and b would be achievable to a person having ordinary skill in the art based on the examples, Appellants do not show how such a person would arrive at the numerical values of a and b . A showing would have perhaps strengthened this argument. Last, and most importantly perhaps, the claims are **not** limited to the working examples taught in the instant specification.

Point 3: Whether appellants are entitled to be their own lexicographer in defining the terms a, b, and c.

Appellants argue that an applicant is entitled to be their own lexicographer and cite numerous case law decisions which provide precedent to this. While the Examiner does not disagree with the principle, the instant disclosure does not clearly convey what the definition of subunits a, b, and c is. A person having ordinary skill in the art readily appreciates and

recognizes that when describing repeat units in polymers or oligomers, a subunit (most commonly referred to by a subscript n) will be clearly linked with a numerical range, which at the very least defines a lower limit for said value of n . Merely referring to the structure as having repeat units does not clearly convey the value of n . Such is the case here. Applicants have not provided a clear and working definition which describes the metes and bounds of subunits a, b, and c. In the absence of any working definition, the broadest reasonable interpretation of a, b, and c allows for one or all of these variables to be equal to zero (which is a number as defined by Appellants in the instant specification). Further, Appellants have adequately described the numerical ranges for the other repeat subunits (subunits n, m, and p). In so doing, Appellants have provided an inconsistent terminology when describing the repeat units which is believed to weaken the arguments presented in point 3.

Point 4: Whether Appellants definition of a, b, and c is sufficient to satisfy 35 U.S.C. 112, first paragraph.

For reasons discussed above, it is believed by the Examiner that the Appellants definition of a, b, and c in the disclosure is not sufficient to satisfy the 112, first paragraph, written description requirement.

Point 5: Whether the Examiner has provided extrinsic evidence showing that appellant's definition of a, b, and c is contrary to the customary or usual practice in the art.

The issue at hand is not whether the Appellants definition of a, b, and c in the instant specification is contrary to the customary or usual definition in the polymer art, but rather if the information presented in Appellants disclosure satisfies the 112, first paragraph, written

description requirement. For reasons provided above, it is the opinion of the Examiner that this is not the case.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the Examiner in the Related Appeals and Interferences section of this Examiner's answer.

Respectfully submitted,

/Robert S. Loewe/

Patent Examiner, Art Unit 1796

/Randy Gulakowski/

Supervisory Patent Examiner, Art Unit 1796

/Jennifer Michener/

QAS, TC1700